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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,365	04/10/2001	Avram Scheiner	279.280US1	7716

7590 11/08/2002
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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/832,365	SCHEINER ET AL.
	Examiner	Art Unit
	Frances P. Oropeza	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 April 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 April 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4 and 5</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 21, 22, 25, 26 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is unclear because (a) and (b) appear to be identical.

In claim 21, "the rate control module" lacks antecedent basis.

In claims 22, 25 and 26, "the lowpass filter" lacks antecedent basis.

In claim 29, line 17, "the thoracic fluid shift" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 1-12 and 15-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Yerich et al. (US 5562711). Yerich et al. disclose a method and apparatus for rate-responsive cardiac pacing including an implantable pacemaker (10) including a pacing/control circuit (20) to

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provide therapy in response to combined physical and metabolic or blended demand, increasing pacing rate based on increased demand (c 4, ll 1-23), an activity sensor circuit (21) to determine physical demand, and an impedance sensing circuit (22) to determine the metabolic and physiological demand (c 4, ll 31-35 and c 8, ll 21-29). Electrodes are associated with the leads and the canister; it is inherent that the electrodes may be designated as electrodes one, two, three or four or can use the same electrode for multiple purposes to sense or stimulate for pacing or impedance measurement depending on the area of the heart being measured (c 5, ll 46-64, c 7, ll 34-53; c 8, ll 48-52; c 9, ll 44-57). The impedance sensing, reflecting respiratory rate, read as breathing, and tidal volume, is accomplished by measuring minute ventilation using impedance changes in the thoracic cavity (c 2, ll 12-34 and c 8, ll 33-38). It is inherent changes in tidal volume are impacted by fluid shifting to and from the lungs. The impedance can be measured using electrodes and constant-current excitation pulses. The lowpass filtering of the impedance signal yields the respiratory rate while the high pass filtering of the same signal yields the patient's cardiac function (c 8, ll 40-52; c 8, l 66 – c 9, l 10). The low-pass filter has a bandpass of 0.05 to 0.8 Hz (c 9, ll 4-10). Baseline values are defined for the physical and metabolic demand (c 25, ll 3-17). Additional sensors, including cardiac sensors indicating metabolic demand, read to be stroke volume, can be blended to determine the systemic demand (c 4, l 63 - c 5, l 11 and c 3, ll 5-9).

4. Claims 1, 2, 3, 5, 6, 8, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al. (US 5957861). Combs et al. disclose a device (10) with an impedance monitor for discerning edema through the evaluation of respiratory rate. This device is coupled with a pacemaker system to provide therapy (c 3, ll 38-48 and c 4, ll 1-4). The low

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pass filter has a bandpass of 0.05 Hz to 0.5 Hz (c 7, ll 13-15). A movement sensor, a body position sensor and a known sensor system, read to be cardiac stroke portion sensor, can be incorporated to determine the systemic demand (c 5, ll 39-45 and c 12, ll 1-16). Edema in the lungs is noted to impact blood pressure, hence creating hypotension when the pressure is low and hypertension when the pressure is high; abnormal blood pressure may be treated by drugs (c 8, ll 37-48). Baseline impedance is determined with adequate sampling (c 7, ll 16-33).

5. Claims 1-8, 13-20 and 30 are rejected under 35 U.S.C. 102 (e) as being anticipated by Pitts Crick et al. (US 6104949). Pitts Crick et al. disclose an implantable pulse generator system to diagnosis and treat congestive heart failure by sensing transthoracic impedance (42) as well as position (99) and relating these values to the baseline value (c 2, l 35 – c 3, l 9). The breathing is inherently detected based on the impedance measurement, indicating the degree of edema (c 2, ll 29-40). The therapy involves increasing the heart rate by heart stimulation, providing systemic drugs or both (c 6, ll 11-30). A higher frequency component of the impedance signal is analyzed (c 4, ll 40-47). The baseline is determined based on averages (c 4, ll 30-34 and c 5, ll 36-51). Electrodes are associated with the leads and the canister; it is inherent that the electrodes may be designated as electrodes one, two, three or four or can use the same electrode for multiple purposes to sense or stimulate for pacing or impedance measurement depending on the area of the heart being measured (c 3, ll 21-64).

6. Claims 1-8, 13-20 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Erlebacher et al. (US 6473640). Erlebacher et al. disclose an implanted device (1) for long-term detection and monitoring of congestive heart failure. A pacemaker generates signals and obtains a dual frequency signal that can measure venous impedance and pulmonary impedance,

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pulmonary impedance being indicative of pulmonary edema and the associate fluid shifts (c 2, ll 37-54 and c 4, ll 7-18). Changes in the impedance measurements over time provide a baseline (c 4, ll 19-30). The pacemaker rate is increased to reduce the congestion in the lungs; drug therapy can also be used (c 5, ll 48-61). Electrodes are associated with the leads and the canister; the electrodes may be designated as electrodes one, two, three or four or can use the same electrode for multiple purposes to sense or stimulate for pacing or impedance measurement depending on the area of the heart being measured (c 5, ll 51-55; c 6, ll 20-51). An accelerometer may be included to determine the impact of activity and posture on the impedance measurement (c 9, l 46 - c 10, l 18).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

JPO
11/2/02

JEFFREY R. JASTRZAB
EXAMINER
3762
11/5/02